

1 MEDICATION GUIDE**2 PEG-Intron™ (Peginterferon alfa-2b)****3 Powder for Injection**

4
5 Read this Medication Guide carefully before you start taking PEG-Intron (**Peg In-tron**) or
6 PEG-Intron/REBETOL (**REB-eh-tole**) combination therapy. Read the Medication Guide
7 each time you refill your prescription because there may be new information. The
8 information in this Medication Guide does not take the place of talking with your doctor.

9
10 **If you are taking PEG-Intron/REBETOL combination therapy, also read the**
11 **Medication Guide for REBETOL (ribavirin, USP) Capsules.**

12
13 **What is the most important information I should know about PEG-Intron and PEG-**
14 **Intron/REBETOL combination therapy?**

15
16 PEG-Intron is a treatment for some people who are infected with hepatitis C virus. However,
17 PEG-Intron and PEG-Intron/REBETOL combination therapy can have serious side effects
18 that may cause death in rare cases. Before you decide to start treatment, you should talk to
19 your doctor about the possible benefits and side effects of PEG-Intron or PEG-
20 Intron/REBETOL combination therapy. If you begin treatment you will need to see your
21 doctor regularly for medical examinations and lab tests to make sure your treatment is
22 working and to check for side effects.

23
24 **REBETOL capsules may cause birth defects and/or death of an unborn child. If you**
25 **are pregnant, you or your male partner must not take PEG-Intron/REBETOL**
26 **combination therapy. You must not become pregnant while either you or your partner**
27 **are being treated with the combination PEG-Intron/REBETOL therapy, or for 6**
28 **months after stopping therapy. Men and women should use birth control while taking**
29 **the combination therapy and for 6 months afterwards. If you or your partner are being**
30 **treated and you become pregnant either during treatment or within 6 months of**
31 **stopping treatment, call your doctor right away.**

32
33 **If you are taking PEG-Intron or PEG-Intron/REBETOL you should call your doctor**
34 **immediately if you develop any of these symptoms:**

35
36 **New or worsening mental health problems such as thoughts about killing or hurting**
37 **yourself or others, trouble breathing, chest pain, severe stomach or lower back pain,**
38 **bloody diarrhea or bloody bowel movements, high fever, bruising, bleeding, or**
39 **decreased vision.**

40
41 The most serious possible side effects of PEG-Intron and PEG-Intron/REBETOL include:

42
43 **Problems with Pregnancy. Combination PEG-Intron/REBETOL therapy can cause**
44 **death, serious birth defects, or other harm to your unborn child. If you are a woman**
45 **of childbearing age you must have negative pregnancy tests immediately before**
46 **beginning treatment, during treatment and for 6 months after you have stopped**



47 **therapy. Female patients must use two effective forms of birth control during**
48 **treatment and for the 6 months after treatment is completed. Male patients should use**
49 **a condom.** You must use birth control even if you believe that you are not fertile or that
50 your fertility is low. You should talk to your doctor about birth control for you and your
51 partner.

52

53 **Mental health problems and suicide.** PEG-Intron and PEG-Intron/REBETOL therapies
54 may cause patients to develop mood or behavioral problems. These can include irritability
55 (getting easily upset) and depression (feeling low, feeling bad about yourself, or feeling
56 hopeless). Some patients may have aggressive behavior. Former drug addicts may fall back
57 into drug addiction or overdose. Some patients think about hurting or killing themselves or
58 other people and some have killed (suicide) or hurt themselves or others. You must tell your
59 doctor if you are being treated for a mental illness or had treatment in the past for any mental
60 illness, including depression and suicidal behavior. You should tell your doctor if you have
61 ever been addicted to drugs or alcohol.

62

63 **Heart problems.** Some patients taking PEG-Intron or PEG-Intron/REBETOL may develop
64 problems with their heart, including low blood pressure, fast heart rate, and very rarely, heart
65 attacks. Tell your doctor if you have had any heart problems in the past.

66

67 **Blood problems.** PEG-Intron and PEG-Intron/REBETOL therapies commonly lower two
68 types of blood cells (white blood cells and platelets). In some patients, these blood counts
69 may fall to dangerously low levels. If your blood counts become very low, this could lead to
70 infections or bleeding.

71

72 REBETOL therapy causes a decrease in the number of red blood cells you have (anemia).
73 This can be dangerous, especially for patients who already have heart or circulatory
74 (cardiovascular) problems. Talk with your doctor before taking combination PEG-
75 Intron/REBETOL therapy if you have or have ever had any cardiovascular problems.

76

77 **Body organ problems.** Certain symptoms like severe stomach pain may mean that your
78 internal organs are being damaged.

79

80 *For other possible side effects, see “What are the possible side effects of PEG-Intron and*
81 *PEG-Intron/REBETOL” in this Medication Guide.*

82

83 **What is PEG-Intron and PEG-Intron/REBETOL combination therapy?**

84 PEG-Intron is a drug used to treat adults who have a lasting (chronic) infection with hepatitis
85 C virus and who show signs that the virus is damaging the liver. PEG-Intron/REBETOL
86 combination therapy consists of two medications also used to treat hepatitis C infection.
87 Patients with hepatitis C have the virus in their blood and in their liver. PEG-Intron reduces
88 the amount of virus in the body and helps the body's immune system fight the virus.
89 REBETOL is a drug that helps to fight the viral infection but does not work when used by
90 itself to treat chronic hepatitis C.

91



92 It is not known if PEG-Intron or PEG-Intron/REBETOL can cure hepatitis C (permanently
93 eliminate the virus) or if it can prevent liver failure or liver cancer that is caused by hepatitis
94 C infection.

95
96 It is also not known if PEG-Intron or PEG-Intron/REBETOL combination therapy will
97 prevent one infected person from infecting another person with hepatitis C.

98

99 **Who should not take PEG-Intron or PEG-Intron/REBETOL therapy?**

100 Do not take PEG-Intron or PEG-Intron/REBETOL therapy if you:

- 101 • are pregnant, planning to get pregnant during treatment or during the 6 months after
102 treatment, or breast feeding
- 103
- 104 • are a male patient with a female sexual partner who is pregnant or plans to become
105 pregnant at any time while you are being treated with REBETOL or during the 6
106 months after your treatment has ended.
- 107
- 108 • have hepatitis caused by your immune system attacking your liver (autoimmune
109 hepatitis) or unstable liver disease
- 110
- 111 • had an allergic reaction to another alpha interferon or are allergic to any of the
112 ingredients in PEG-Intron or REBETOL Capsules. (See ingredients listed at the end
113 of this Medication Guide).
- 114
- 115 • Do not take PEG-Intron/REBETOL combination therapy if you have abnormal red
116 blood cells such as sickle-cell anemia or thalassemia major.
- 117

118 **If you have any of the following conditions or serious medical problems, discuss them
119 with your doctor before taking PEG-Intron or PEG-Intron/REBETOL:**

- 120 • depression or anxiety
- 121 • sleep problems
- 122 • high blood pressure
- 123 • previous heart attack, or other heart problems
- 124 • liver problems (other than hepatitis C infection)
- 125 • any kind of autoimmune disease (where the body's immune system attacks the body's
126 own cells), such as psoriasis, systemic lupus erythematosus, rheumatoid arthritis
- 127 • thyroid problems
- 128 • diabetes
- 129 • colitis (inflammation of the bowels)
- 130 • cancer
- 131 • hepatitis B infection
- 132 • HIV infection
- 133 • kidney problems
- 134 • bleeding problems
- 135 • alcoholism
- 136 • drug abuse or addiction



- 137 • body organ transplant and are taking medicine that keeps your body from rejecting your
138 transplant (suppresses your immune system).
139

140
141 **How should I take PEG-Intron or PEG-Intron/REBETOL?**

142 Your doctor will decide whether you will take PEG-Intron alone or the combination of PEG-
143 Intron/REBETOL, as well as the correct dose (based on your weight). PEG-Intron and PEG-
144 Intron/REBETOL are given for one year. Take your prescribed dose of PEG-Intron once a
145 week, on the same day of each week and at approximately the same time. Take the medicine
146 for the full year and do not take more than the prescribed dose. REBETOL Capsules should
147 be taken with food. When you take REBETOL with food, more of the medicine (70% more
148 on average) is taken up by your body. You should take REBETOL the same way every day
149 (twice a day with food) to keep the medicine in your body at a steady level. This will help
150 your doctor to decide how your treatment is working and how to change the number of
151 REBETOL capsules you take if you have side effects from REBETOL. **Be sure to read**
152 **the Medication Guide for REBETOL (ribavirin, USP) for complete instructions on how**
153 **to take the REBETOL capsules.**
154

155 You should be completely comfortable with how to prepare PEG-Intron; how to measure the
156 dose you take; and how to inject yourself before you use PEG-Intron for the first time. Your
157 health care provider will train you in the proper techniques for doing this. See the section
158 “How do I prepare and inject the PEG-Intron dose” below for written instructions.
159

160 If you miss a dose of PEG-Intron, take the missed dose as soon as possible during the same
161 day or the next day, then continue on your regular dosing schedule. If several days go by
162 after you miss a dose, check with your doctor about what to do. Do not double the next dose
163 or take more than one dose a week without talking to your doctor. Call your doctor right
164 away if you take more than your prescribed PEG-Intron dose. Your doctor may wish to
165 examine you more closely, and take blood for testing.
166

167 If you miss a dose of REBETOL, take the missed dose as soon as possible during the same
168 day. If an entire day has gone by, check with your doctor about what to do. Do not double
169 the next dose.
170

171 You must get regular blood tests to help your doctor check how the treatment is working and
172 to check for side effects.
173

174 Tell your doctor if you are taking or planning to take other prescription or non-prescription
175 medicines, including vitamin and mineral supplements and herbal medicines.
176

177 **What should I avoid while taking PEG-Intron or PEG-Intron/REBETOL therapies?**

- 178 • If you are pregnant do not start taking PEG-Intron/REBETOL combination therapy.
179 • Avoid becoming pregnant while taking PEG-Intron or PEG-Intron/REBETOL. PEG-
180 Intron and PEG-Intron/REBETOL may harm your unborn child (death or serious birth
181 defects) or cause you to lose your baby (miscarry). **If you or your partner become**
182 **pregnant during treatment or during the 6 months after treatment with PEG-**



183 **Intron/REBETOL combination therapy, immediately report the pregnancy to your**
184 **doctor. You or your doctor should call (800) 727-7064.** By calling this number,
185 information about you and/or partner will be added to a pregnancy registry that will be
186 used to help you and your doctor make decisions about your treatment for Hepatitis in
187 the future. You, your partner and/or your physician will be asked to provide follow-up
188 information on the outcome of the pregnancy.

- 189
- 190 • Do not breastfeed your baby while taking PEG-Intron.
- 191

192 **What are the possible side effects of PEG-Intron and PEG-Intron/REBETOL**
193 **combination therapy?**

194

195 **Possible, serious side effects include:**

196 **Mental health problems including suicide, blood problems, heart problems, body organ**
197 **problems.** See “What is the most important information I should know about PEG-Intron
198 and PEG-Intron/REBETOL combination therapy?”

199

200 **Other body organ problems.** A few patients have lung problems (such as pneumonia or
201 inflammation of the lung tissue), inflammation of the kidney, and eye disorders.

202

203 **New or worsening autoimmune disease.** Some patients taking PEG-Intron or PEG-
204 Intron/REBETOL develop autoimmune diseases (a condition where the body’s immune cells
205 attack other cells or organs in the body), including rheumatoid arthritis, systemic lupus
206 erythematosus, and psoriasis. In some patients who already have an autoimmune disease, the
207 disease worsens on PEG-Intron and PEG-Intron/REBETOL combination therapy.

208

209 **Common but less serious side effects include:**

210

211 **Flu-like symptoms.** Most patients who take PEG-Intron or PEG-Intron/REBETOL have
212 "flu-like" symptoms (headache, muscle aches, tiredness and fever). Some of these symptoms
213 (fever, headache) usually lessen after the first few weeks of therapy. You can reduce some of
214 these symptoms by injecting your PEG-Intron dose at bedtime. Over-the-counter pain and
215 fever reducers, such as acetaminophen or ibuprofen, can be used to prevent or reduce the
216 fever and headache.

217

218 **Extreme fatigue (tiredness).** Many patients become extremely tired while on PEG-Intron or
219 PEG-Intron/REBETOL combination therapy.

220

221 **Appetite problems.** Nausea, loss of appetite, and weight loss, occur commonly.

222

223 **Thyroid problems.** Some patients develop changes in the function of their thyroid.
224 Symptoms of thyroid changes include the inability to concentrate, feeling cold or hot all the
225 time, a change in your weight and changes to your skin.

226

227 **Blood sugar problems.** Some patients develop problems with the way their body controls
228 their blood sugar and may develop high blood sugar or diabetes.



229

230 **Skin reactions.** Redness, swelling, and itching are common at the site of injection. If after
231 several days these symptoms do not disappear contact your doctor. You may get a rash
232 during therapy. If this occurs, your doctor may recommend medicine to treat the rash.

233

234 **Hair thinning.** Hair thinning is common during PEG-Intron and PEG-Intron/REBETOL
235 treatment. Hair loss stops and hair growth returns after therapy is stopped.

236

237 These are not all of the side effects of PEG-Intron or PEG-Intron/REBETOL combination
238 therapy. Your doctor or pharmacist can give you a more complete list.

239

240 **How do I prepare and inject the PEG-Intron Dose?**

241 Before you inject PEG-Intron, the powder must be mixed with **0.7 mL** of the supplied
242 DILUENT for PEG-Intron, Sterile Water for Injection (diluent). You should carefully follow
243 the directions given to you by your doctor. After you have mixed the diluent and powder,
244 and the solution is completely dissolved, it should be clear, colorless and without particles.
245 Do not use it if you see particles or the color is not correct; call your doctor, nurse, or
246 pharmacist.

247

248 The vial of mixed PEG-Intron should be used immediately, so **DO NOT** prepare more than
249 one vial at a time.

250

251 **Preparing the PEG-Intron solution**

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253 1. Check the date printed on the PEG-Intron carton to make sure that the expiration date has
254 not passed.

255

256 2. Wash your hands thoroughly with soap and water, rinse and towel dry.

257

258 3. The supplies you will need are provided in the PEG-Intron package; you should place
259 them on a clean work area. The PEG-Intron package contains a vial of PEG-Intron
260 powder, a 5-mL vial of DILUENT, 2 disposable syringes, and alcohol swabs. These
261 syringes have a needle already attached that cannot be removed and are for single use
262 only.

263

264 The disposable syringe provided has a clear plastic safety sleeve that is pulled over the
265 needle after use for disposal. Figure A indicates the safety sleeve as well as the other
266 parts referred to in these instructions. The safety sleeve should be tight against the flange
267 for use and moved over the needle only when ready for disposal, as instructed in step 18.

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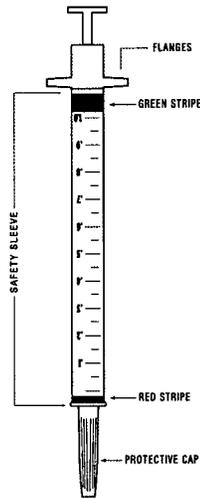


Figure A

4. Remove the protective wrapper from ONE of the syringes provided and use for the following steps 5-7.

5. Remove the protective plastic cap from the tops of both the supplied DILUENT and the PEG-Intron vials. Clean the rubber stopper on the top of both vials with an alcohol swab.

6. Remove the protective cap from the needle and fill the syringe with air by pulling the plunger to 0.7 mL (Figure B). Hold the DILUENT vial upright. Do not touch the cleaned top of the vial with your hands. (Figure C). Insert the needle through the rubber stopper of the DILUENT vial, and inject the air in the syringe into the vial (Figure D). Turn the vial upside down and make sure the tip of the needle is in the liquid. **Withdraw only 0.7 mL of DILUENT** by pulling the plunger back to exactly 0.7 mL (Figure E). The marks on the side of the syringe indicate the amount of DILUENT to withdraw. Remove the needle from the vial (Figure F). **Discard the remaining DILUENT.**



Figure B

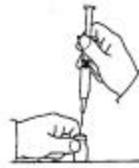


Figure C



Figure D

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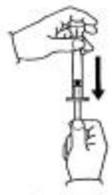


Figure E



Figure F

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306 7. Insert the needle through the rubber stopper of the PEG-Intron vial, and place the needle
307 tip against the glass wall of the vial (Figure G). Slowly inject the 0.7 mL DILUENT, so that
308 it runs down the glass. To prevent producing bubbles, **DO NOT AIM THE STREAM AT**
309 **THE WHITE POWDER** in the bottom of the vial. Remove the needle from the vial, pull the
310 safety guard over the needle, and dispose as instructed in step 18 below. A new syringe will
311 be used for injection of the medication.

312

313 Swirl the vial with a gentle circular motion (Figure H), until the PEG-Intron powder is
314 completely dissolved. If the solution is cold, warm the vial by gently rolling it between your
315 hands. If air bubbles do form, wait until the solution has settled and all bubbles have risen to
316 the top of the solution and disappeared before withdrawing your dose from the vial.

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Figure G



Figure H

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329 8. When the PEG-Intron powder is completely dissolved it will be clear, colorless and
330 without particles. Do not use it if you see particles or the color is not correct; call your
331 doctor, nurse, or pharmacist.

332

333 9. The solution of PEG-Intron contains no preservatives and should be used immediately.

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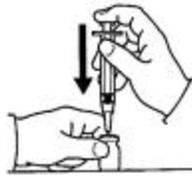
335 10. After the PEG-Intron powder is dissolved, clean the vial's rubber stopper with an alcohol
336 swab again.

337

338 11. Take the second syringe provided and unwrap it. You will use it to give yourself the
339 injection. Remove the protective cap from the needle and fill the syringe with air by pulling
340 the plunger to the number (**mL**) that corresponds to your prescribed dose (Figure J). Hold
341 the PEG-Intron vial upright. **DO NOT** touch the cleaned top of the vial with your hands
342 (Figure K). Insert the needle into the vial containing the PEG-Intron solution and inject the
343 air into the vial. (Figure L).



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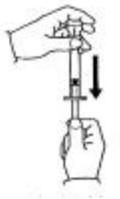
Figure J

Figure K

Figure L

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12. Turn the PEG-Intron vial upside down. Be sure the tip of needle is in the Peg-Intron solution. While holding the vial and syringe with one hand slowly pull the plunger back to withdraw into the syringe the exact amount of PEG-Intron your doctor told you to use (Figure M).

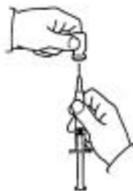


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Figure M

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13. Remove the needle from the vial (Figure N) and check for air bubbles in the syringe. If you see any bubbles, hold the syringe with the needle pointing up and tap the syringe gently until the bubbles rise. Then push the plunger in slowly until the bubbles disappear.



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Figure N

Injecting the PEG-Intron Dose

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14. Selecting the Site for Injection.

- The best sites for giving yourself an injection are those areas with a layer of fat between the skin and muscle, like your thigh, the outer surface of your upper arm, and abdomen.



372 Do not inject yourself in the area near your navel or waistline. If you are very thin, you
373 should only use the thigh or outer surface of the arm for injection.

374

- 375 • Do not inject PEG-Intron solution in the same place all the time. You should change
376 your injection site each time in a regular pattern.

377

378 15. Clean the skin where the injection is to be given with an alcohol swab, and wait for the
379 area to dry. Remove the protective cap from the needle. Make sure the safety sleeve of the
380 syringe is pushed firmly against the syringe flange so that the needle is fully exposed (see
381 Figure A.).

382

383 16. With one hand, pinch a 2-inch fold of loose skin. With your other hand, pick up the
384 syringe and hold it like a pencil. Position the bevel of the needle facing up and insert the
385 needle approximately ¼ inch into the pinched skin at approximately a 45 to 90 degree angle
386 with a quick dart-like thrust. After the needle is in, remove the hand that you used to pinch
387 your skin and use it to hold the syringe barrel. Pull the plunger of the syringe back very
388 slightly. If blood comes into the syringe, the needle has entered a blood vessel. **Do not**
389 **inject.** Withdraw the needle and discard the syringe as outlined in step 18. Repeat the above
390 steps with a new vial to prepare a new syringe and inject the medicine at a new site. If no
391 blood is present in the syringe, inject the medicine by gently pressing the plunger all the way
392 down the syringe barrel.

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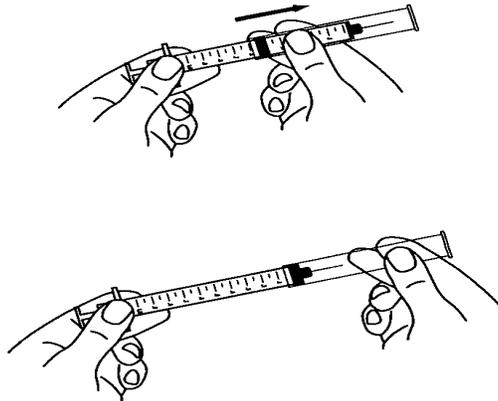
394 17. Hold an alcohol swab near the needle and pull the needle straight out of the skin. Press
395 the alcohol swab over the injection site for several seconds. Do not massage the injection
396 site. If there is bleeding, cover it with a bandage.

397

398 18. After use, firmly grasp the safety sleeve and pull over the exposed needle until you hear
399 a click, and the green stripe on the safety sleeve covers the red stripe on the needle (Figure
400 O). Discard the syringe and needle after each use in the Sharp's container supplied to you.
401 The full container should be disposed of according to the directions provided by your doctor
402 or nurse. Do not leave used supplies or the Sharp's container in an open area.



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416 Figure O

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19. After 2 hours, check the injection site for redness, swelling, or tenderness. If you have a skin reaction and it doesn't clear up in a few days, contact your doctor or nurse.

422

Storing PEG-Intron

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PEG-Intron Powder should be stored at room temperature (25 ° C, 77°F); avoid exposure to heat. After mixing, the PEG-Intron solution should be used immediately but may be stored in the refrigerator up to 24 hours. The solution contains no preservatives. Do not freeze.

427

General advice about prescription medicines:

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Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you have any concerns about PEG-Intron, ask your doctor. Your doctor or pharmacist can give you information about PEG-Intron that was written for health care professionals. Do not use PEG-Intron for a condition for which it was not prescribed. Do not share this medication with other people.

433

Ingredients:

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PEG-Intron: pegylated interferon alfa-2b, dibasic sodium phosphate, monobasic sodium phosphate, sucrose, and polysorbate 80.

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If you are taking PEG-Intron/REBETOL combination therapy, also read the Medication Guide for REBETOL (ribavirin, USP) Capsules.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

443

Manufactured by: Schering Corporation, Kenilworth, NJ 07033 USA

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Revised: **DATE**

